

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

FEDERAL TRADE COMMISSION,

Plaintiff,

v.

ABBVIE INC., et al.,

Defendants.

Case Number: 2:14-CV-5151-HB

**Reply Memorandum in Support of Plaintiff Federal Trade Commission's Motion to
Compel Defendants to Correct Deficient Interrogatory Answers**

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Defendants' opposition does nothing to justify the shortcomings in their interrogatory responses. Defendants object to the interrogatories at issue on the ground that they seek information outside the prosecution history record. (*See* Dkt. 198 at 6-7.) But Defendants have already demonstrated their willingness to rely on material outside the prosecution history record in contending that they had reasonable arguments to overcome prosecution history estoppel. (*See, e.g.*, Dkt. 59 at 29-30.) The interrogatories at issue are designed to discover whether Defendants will likewise seek to rely on material outside the prosecution history record with respect to: (1) their basis for statements in written remarks to the patent examiner during the '894 patent prosecution and (2) their purported rationale for why Teva's penetration enhancer was not included in amended claim 1 of the October 2001 amendment. In addition, Defendants ignore the fact that information outside the prosecution history record is relevant to the second part of the sham litigation standard.¹

I. Interrogatory No. 22 properly seeks facts relevant to matters Defendants have put at issue.²

Interrogatory No. 22 asks Defendants to identify facts regarding the unexpected results or other secondary considerations for a testosterone gel composition containing isostearic acid ("ISA") or isopropyl palmitate ("IPP")—the penetration enhancers in Perrigo's and Teva's products, respectively. (*See, e.g.*, Dkt. 188-4 at 4.) Defendants assert that these facts are irrelevant because the FTC does not challenge the validity of the '894 patent. (Dkt. 198 at 3.) This argument, however, is a red herring.

¹ The Court has already recognized in this case that discovery regarding how the patent was "perceived . . . at the time it was issued" is relevant to the two-part test for sham litigation. (*See* Dkt. 145 at 36.)

² The same interrogatory was propounded to Besins as Interrogatory No. 15.

Defendants are well aware that Unimed and Besins asserted “secondary considerations” (*i.e.*, objective indicia of non-obviousness) in their remarks to the patent examiner in an effort to overcome her obviousness rejection. (*See* Dkt. 59-10 at UCFH 1974-75, UCFH 1980-81.) As noted in our opening brief, Unimed and Besins argued that the patent examiner should allow a claim encompassing 24 specific penetration enhancers because the unexpected results for the “claimed composition” should overcome the patent examiner’s obviousness rejection.³ (Dkt. 59-10 at UCFH 1974 (“Significantly, the unexpected and unique pharmacokinetic and pharmacodynamic profile of the claimed composition is not taught or suggested by the cited references or prior art.”).) But Unimed and Besins only presented evidence of such secondary considerations for a testosterone gel composition with isopropyl myristate (“IPM”) as the penetration enhancer, namely, AndroGel. (*See* Dkt. 59-10 at UCFH 1974-75; Dkt. 188-6 at UCFH 1986.) Ultimately, they narrowed their patent claims to a testosterone gel composition with IPM as the sole penetration enhancer, the only composition that their unexpected results supported. (*See* Dkt. 59-12 at UCFH 2041-42 (listing amended claims 47 and 61).)

Accordingly, Defendants cannot rest on a relevance objection to avoid answering this interrogatory. The interrogatory relates not to the validity of an issued patent but to the U.S. Patent and Trademark Office’s decision to ultimately grant the ’894 patent after a series of narrowing amendments. As explained in our opening brief, these interrogatories are relevant to both prongs of the sham litigation standard. (*See* Dkt. 188-1 at 5 n.9.) Whether Unimed and Besins narrowed the penetration enhancer element of the claimed composition to IPM alone for

³ At the time they made this statement, the claimed composition included ISA but not IPP. (*See* Dkt. 59-10 at UCFH 1962 (listing amended claim 1).) However, Defendants have asserted that “[a]ll of the inventors’ arguments for patentability would have applied equally if isopropyl palmitate had been literally claimed in the claims proposed in the amendment of October 19, 2001.” (Dkt. 188-7 at 17; Dkt. 188-8 at 16.) Thus, Defendants have asserted that their arguments about unexpected results applied equally to IPP.

reasons of patentability relates to the first prong of the sham litigation standard. The interrogatories are also relevant to Defendants' awareness of the role that unexpected results evidence played in obtaining the '894 patent.

II. Defendants' restrictive interpretation of Interrogatory No. 22 is inconsistent with their obligation to provide a full and complete response under the federal rules.

Defendants freely acknowledge that they provided no citations to documents or other evidentiary support for any of the purported facts identified in their interrogatory response. (*See* Dkt. 198 at 4-5.) Defendants nonetheless insist that their response is complete because the "interrogatory asked Defendants to [identify facts]" and "Defendants provided facts." (*Id.* at 4.) Defendants' position is inconsistent with "the letter and spirit of the federal rules."⁴

The purpose of discovery is to "narrow and clarify the basic issues between the parties" and to "ascertain[] the facts, or information as to the existence or whereabouts of facts, relative to those issues."⁵ Consistent with this objective, the Federal Rules of Civil Procedure require a party to answer an interrogatory "fully."⁶ This obligation means that a "party responding to an interrogatory 'must furnish information that is available to it and that can be given without undue labor and expense.'"⁷ "Interrogatories . . . should not be read or interpreted in an artificially restrictive or hypertechnical manner to avoid disclosure of information fairly covered by the discovery request."⁸ Defendants presumably are aware of the documents and other evidence that support the facts cited in their interrogatory response, to the extent such evidence even exists. To

⁴ *Younes v. 7-Eleven, Inc.*, 312 F.R.D. 692, 705 (D.N.J. 2015).

⁵ *Hickman v. Taylor*, 329 U.S. 495, 501 (1947).

⁶ Fed. R. Civ. P. 33(b)(3).

⁷ *Lynn v. Monarch Recovery Mgmt., Inc.*, 285 F.R.D. 350, 357 (D. Md. 2012) (*quoting* 8B Charles Alan Wright et al., *Fed. Prac. & Proc. Civ.* § 2174 (3d ed. 2012)).

⁸ *Younes*, 312 F.R.D. at 709 (internal citations omitted).

respond “fully” to the interrogatory, they should provide it. Defendants offer no reason why doing so would be unduly burdensome. Of course, to the extent no such evidence exists, Defendants should simply say so.

III. Defendants should be precluded from contending whether the omission of IPP from amended claim 1 in the October 2001 amendment was inadvertent or a drafting error later in this case.

As Defendants acknowledge, Interrogatory No. 23 is a contention interrogatory.⁹ (Dkt. 198 at 5.) It asks a straightforward question: Do Defendants contend that the omission of IPP from amended claim 1 in the October 2001 amendment was inadvertent or a drafting error? (*See, e.g.*, Dkt. 188-4 at 4.) Defendants refused to provide a simple “yes” or “no” answer even though, as they now assert, they “do not have contentions, positive or negative, on the topic of [the interrogatory].” (Dkt. 198 at 6.) If Defendants have no contentions, “positive or negative,” on this topic, then the appropriate answer to the contention interrogatory would appear to be “no.” In any event, because Defendants have no contentions, “positive or negative,” on whether the failure to include IPP in the October 2001 amendment was inadvertent or a drafting error, they should be precluded from raising any contentions on this topic in the future.

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Respectfully submitted,

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⁹ The same interrogatory was propounded to Besins as Interrogatory No. 16.

Certificate of Service

I hereby certify that on July 21, 2016, I caused the Reply Memorandum in Support of Plaintiff Federal Trade Commission's Motion to Compel Defendants to Correct Deficient Interrogatory Answers to be filed with the United States District Court for the Eastern District of Pennsylvania using the ECF system. I certify that I also caused this filing to be served on all counsel of record via electronic mail.

/s/ Patricia M. McDermott
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